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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/054,534	01/22/2002	Pradip Mukerji	6763.US.P1	3165
23492	7590	10/28/2004	EXAMINER	
ROBERT DEBERARDINE ABBOTT LABORATORIES 100 ABBOTT PARK ROAD DEPT. 377/AP6A ABBOTT PARK, IL 60064-6008			SULLIVAN, DANIEL M	
			ART UNIT	PAPER NUMBER
			1636	
DATE MAILED: 10/28/2004				

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/054,534	Applicant(s) MUKERJI ET AL.
	Examiner Daniel M Sullivan	Art Unit 1636

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 August 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2 and 4-36 is/are pending in the application.
- 4a) Of the above claim(s) 1,6-10 and 17-35 is/are withdrawn from consideration.
- 5) ☒ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 2,4,5,11-16 and 36 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>6/4/04</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

This Office Action is a reply to the Paper filed 23 August 2004 in response to the Non-Final Office Action mailed 30 December 2003. Claims 1, 6-10 and 17-35 were withdrawn from consideration and claims 2-5 and 11-16 were considered in the 30 December Office Action. Claim 3 was canceled, claims 2, 4, 5, 11, 12 and 14-16 were amended and claim 36 was added in the 23 August Paper. Claims 1, 2 and 4-36 are presently pending and claims 2, 4, 5, 11-16 and 36 are under consideration.

Response to Amendment

Specification

The specification stands objected to because it contains references to dates and deposit numbers that are not specified (e.g., page 69, lines 14 and 16). The reply did not address this aspect of the objection.

Claim Objections

Objection to claims 2, 4, 5 and 11-16 as containing informalities is withdrawn in view of the amendments to the claims.

Double Patenting

Claims 2, 4, 5 and 11-16 stand provisionally rejected and newly added claim 36 is provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-5, 10, 16, 17 and 20 of copending Application No.

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10/431,952 (hereinafter, '952). In the reply, Applicant requested that the rejection be held in abeyance until such time as allowable subject matter is noted in either application. The claims will stand rejected until such time as the rejection is properly addressed.

Claim Rejections - 35 USC § 112, first paragraph

Rejection of claims 2, 4 and 5 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement is withdrawn in view of the amendments to the claims and arguments of record.

Claims 2, 4 and 5 stand rejected and newly added claim 36 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for an isolated nucleic acid encoding a polypeptide having 70% sequence identity with SEQ ID NO: 14, wherein said nucleic acid encodes a functionally active Δ -6 desaturase, does not reasonably provide enablement for any nucleic acid sequence comprising at least 70% sequence to a nucleotide sequence comprising SEQ ID NO: 13 or encoding any desaturase having 70% amino acid sequence identity to an amino acid sequence comprising SEQ ID NO: 14. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make or use the invention commensurate in scope with these claims. The claims are rejected for reasons of record and herein below in the response to arguments.

Claims 11 and 13 stand rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of producing a desaturase in a host cell *in vitro*

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and an isolated host cell comprising a vector comprising the nucleic acid set forth as SEQ ID

NO: 13, does not reasonably provide enablement for the method or host cell *in vivo* for reasons of record and herein below in the response to arguments.

Claim Rejections - 35 USC § 112, first paragraph

Rejection of claim 11 under 35 U.S.C. 112, second paragraph, as being indefinite is withdrawn.

Response to Arguments

Claim Rejections - 35 USC § 112, first paragraph

Claims 2, 4 and 5 stand rejected and newly added claim 36 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for an isolated nucleic acid encoding a polypeptide having 70% sequence identity with SEQ ID NO: 14, wherein said nucleic acid encodes a functionally active Δ -6 desaturase, does not reasonably provide enablement for any nucleic acid sequence comprising at least 70% sequence identity to a nucleotide sequence comprising SEQ ID NO: 13 or encoding any desaturase having 70% amino acid sequence identity to an amino acid sequence comprising SEQ ID NO: 14.

It was indicated in the previous Office Action that the disclosure was not enabling beyond the scope of an isolated nucleic acid comprising SEQ ID NO: 13 or a nucleic acid encoding SEQ ID NO: 14, wherein said nucleic acid encodes a functionally active Δ -6 desaturase.

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In response to the *prima facie* case of record, Applicant argues that based upon the knowledge of one of ordinary skill in the art, information present in the specification and the relationship between structure and function in connection with delta-6-desaturases from other species, claims 2, 4 and 5 are fully enabled.

This argument has been fully considered and is deemed persuasive to the extent that the claimed nucleic acid comprises the structural limitations set forth in the claims and is limited to encoding a functional delta-6-desaturase. However, the claims stand rejected because the nucleic acid of the rejected claims is not limited to encoding a delta-6-desaturase. As stated in the previous Office Action, the specification provides no guidance that would enable the skilled artisan to use any nucleic acid having at least about 50% [or 70%] sequence identity to the nucleotide sequence set forth as SEQ ID NO: 13. That is, a large portion of the genus of nucleotides claimed in claim 2 and 5 have no desaturase function and, therefore, no enabled use. Although claims 4 and 36 are limited to encoding an active desaturase, the application does not teach how to use a desaturase regardless of its activity (*i.e.*, substrate specificity). Therefore, the skilled artisan would have to resort to undue trial and error experimentation to determine how to use embodiments of the claimed invention that do not have delta-6-desaturase activity.

Applicant's arguments have been fully considered but are not deemed persuasive in view of the record as a whole. Therefore, the claims stand rejected under 35 U.S.C. §112, first paragraph, as lacking enablement for the full scope of the claimed subject matter.

Claims 11 and 13 stand rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of producing a desaturase in a host cell *in vitro*

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and an isolated host cell comprising a vector comprising the nucleic acid set forth as SEQ ID NO: 13, does not reasonably provide enablement for the method or host cell *in vivo*.

In response to the *prima facie* case of record, Applicant asserts that one of skill in the art would certainly have known how to take the nucleic acid of the claims and introduce it into a plant or mammalian cell in order to produce the desired protein.

This argument has been fully considered but is not deemed persuasive because it does not address the grounds for the finding of non-enablement for the scope of *in vivo*. While it is acknowledged that introducing a nucleic acid into a cell is routine, the art teaches that obtaining expression of heterologous proteins *in vivo* to produce genetically modified animals capable of functioning as bioreactors is highly unpredictable. Although, the specification demonstrates functional expression of the $\Delta 6$ -desaturase in yeast, and the art teaches that functional fungal $\Delta 6$ -desaturases can be expressed in mammalian cells, the art also teaches that results obtained in cultured cells cannot readily be extended to *in vivo* expression systems. The specification provides no evidence that the transgenic bioreactor contemplated in the specification can be obtained by expressing the fungal $\Delta 6$ -desaturase *in vivo* without significant empirical experimentation to overcome the art-recognized barriers to obtaining useful *in vivo* expression. Thus, practicing the method of claim 11 *in vivo* or making the cell of claim 13 *in vivo* such that it could be used for the purposes asserted in the specification would require undue experimentation. The art cited by Applicant in the paragraph bridging pages 18-19 does not support Applicant's assertion that the claims are generally enabled for *in vivo* because the cited art does not address the barriers to providing effective transgenic bioreactor expression, which were described in the previous Office Action. None of the cited art provides a working example

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of an *in vivo* bioreactor expressing a delta-6-desaturase and, at best, the art merely provides the same general instruction found in the instant application, which, in view of the state of the art at the time of filing, was not enabling for obtaining useful *in vivo* expression of a desaturase enzyme.

Applicant's arguments have been fully considered but are not deemed persuasive in view of the record as a whole. Therefore, the claims stand rejected under 35 U.S.C. §112, first paragraph, as lacking enablement for the full scope of the claimed subject matter.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

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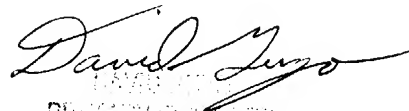
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Daniel M Sullivan whose telephone number is 571-272-0779.

The examiner can normally be reached on Monday through Thursday 6:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel, Ph.D. can be reached on 571-272-0781. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Daniel M Sullivan, Ph.D.
Examiner
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PRIMARY EXAMINER